AMENDMENTS TO THE CLAIMS

1. (Original) Capsules comprising an outer membrane of a divalent or trivalent metal ion salt of alginic acid, and an internal nucleus comprising a suspension of stem cells, genetically modified male and female somatic cells, ovarian follicular cells, gametes, ovarian follicles, mammalian embryos and/or a biocompatible and/or biodegradable polymer constituting an artificial extracellular matrix.

2. (Original) The capsules according to claim 1, wherein said cells are suspended in a gelatinous medium.

3. (Currently Amended) The capsules according to ~~claims 1 or 2~~ claim 1 characterised in that said mammalian stem cells, genetically modified male and female somatic cells, ovarian follicular cells, ovarian follicles, gametes, and mammalian embryos are auto-organised in vitro into three- dimensional parenchymatose, follicular or alveolar type structures, which allow the in vitro growth of tissues and multicellular structures functionally similar to organs present in the whole mammalian organism.

4. (Currently Amended) The capsules according to ~~any of the claims 1 to 3~~ claim 1, characterised in that said stem cells, genetically modified male and female somatic cells, ovarian follicular cells, gametes, ovarian follicles and mammalian embryos are functionally similar to the organs found in the whole organism and able to synthesise and secrete hormones such as progesterone (P4) and 17a-oestradiol (E2) and other biologically active substances in quantities similar to that which said structures produce in vivo.

5. (Currently Amended) The capsules according to ~~any of the claims 1 to 4~~ claim 1 wherein said alginate membrane is gelatinous, bioerodible and is cross-linked on the inner and/or outer surfaces and/or on both surfaces.

6. (Currently Amended) The capsules according to ~~any of the claims 1 to 5~~ claim 1 characterised in that the alginate membrane may be cross-linked using cross-linking agents selected from: protamine sulphate or phosphate, poly-L-lysine bromohydrate, polyvinylamine, or chitosans.

7. (Currently Amended) The capsules according to ~~any of the claims1 to 6~~ claim 1 wherein the outer membrane is constituted by divalent metal alginates selected from: calcium, barium, strontium, zinc or trivalent metals selected from: aluminium, iron, chromium.

8. (Currently Amended) The capsules according to ~~any of the claims 1 to 7~~ claim 1 characterised in that the alginate membrane contains a second or more cellular species.

9. (Original) The capsules according to claim 8 characterised in that the alginate membrane contains ovarian follicular cells, one or more gametes, one or more ovarian follicles and one or more mammalian embryos.

10. (Original) The capsules according to claim 8 characterised in that the alginate membrane contains one or more female gametes also in various stages of development.

11. (Currently Amended) The capsules according to ~~any of the claims 1 to 10~~ claim 1 characterised in that said biocompatible and/or

biodegradable polymer is a hydrophilic polymer selected from the group constituted by: glucans, scleroglucans, mannans, galactomannans, gellans, carrageenans, pectins, polyanhydrides, polyaminoacids, polyamines, xanthans, celluloses and derivatives thereof: carboxymethylcelluloses, ethylcelluloses, methylcelluloses, hydroxypropylcelluloses hydroxypropylmethylcelluloses, polyvinylalcohols, carboxyvinylpolymers, starches, alpha, beta, gamma cyclodextrins and dextrin derivatives in general, collagens, chitins, chitosans, alginic acid, hyaluronic acid.

12. (Original) The capsules according to claim 11, characterised in that said polymers, in aqueous solution, are present in concentrations between 0.01% and 90% of the total capsule weight.

13. (Original) The capsules according to claim 12, characterised in that said polymers, in aqueous solution, are present in concentrations between 0.5% and 50% of the total capsule weight.

14. (Original) The capsules according to claim 12, characterised in that the hydrophilic polymeric material, which constitutes the artificial extracellular matrix of said capsule nucleus, is xanthan gum having viscosity between 800 and 1200 cP.

15. (Currently Amended) The capsules according to ~~any of the claims 1 to 14~~ claim 1 characterised in that said capsules have diameters between 0. 5 mm and 30 mm, with membrane thicknesses between 300 pm and 5000 urn.

16. (Original) The capsules according to claim 15 characterised in that said capsules preferably have diameters between 2 mm and 10 mm.

17. (Currently Amended) The capsules according to ~~any of the claims 1 to16~~ claim 1 characterised in that said capsules weigh between 5 mg and 200 mg.

18. (Original) The capsules according to claim 17 characterised in that said capsules preferably weigh between 20 mg and100 mg.

19. (Currently Amended) A kit for the preparation of capsules according to ~~any of the claims 1 to 18~~ claim 1 comprising disposable, sterile, non-sterile or sterilisable, preset and pre- packaged instrumentation, for single and or multiple preparations.

20. (Original) The kit according to claim 19 comprising salts of a divalent or trivalent ion, an alkaline metal alginate, in separate pre-measured packages.

21. (Original) The kit according to claim 20, further comprising a biocompatible and/or biodegradable hydrophilic polymer preferably selected from: glucans, scleroglucans, mannans, galactomannans, gellans, carrageenans, pectins, polyanhydrides, polyaminoacids, polyamines, xanthans, celluloses and derivatives thereof: carboxymethylcelluloses, ethylcelluloses, methylcelluloses, hydroxypropylcelluloses hydroxypropylmethylcelluloses, polyvinylalcohols, carboxyvinylpolymers, starches, alpha, beta, gamma cyclodextrins and dextrin derivatives in general, collagens, chitins, chitosans, alginic acid, hyaluronic acid.

22. (Currently Amended) The kit according to ~~claims 20 or 21~~ claim 20, further comprising a cross-linking agent preferably selected from protamine sulphate or phosphate, poly-L-lysine bromohydrate, polyvinylamine, or chitosans.

23. (Currently Amended) The kit according to ~~any of the claims 20 to 22~~ claim 20, further comprising a culture medium preferably selected from: physiological solution (isotonic saline), glucosate solution, Basal Medium Eagle (BME) and derivatives thereof, Hanks salts solution and derivatives thereof, tissue culture medium 199 (TCM 199) and derivatives thereof, phosphate buffered saline (PBS) and derivatives thereof, Krebs salts solution and derivatives thereof, Dulbecco modified Eagle's medium (DMEM) and derivatives thereof, tris-buffered medium (TBM) and derivatives thereof, Tyrode's salts solution and derivatives thereof, Modified sperm washing medium, modified human tubal fluid, Modified ham's F-10 medium, Upgraded B2 INRA medium, B2 INRA Menezo Medium, Upgraded B9 medium.

24. (Currently Amended) The kit according to ~~any of the claims 20 to 23~~ claim 20, further comprising extrusion devices such as sterile, non-sterile or sterilisable nozzles, needles or syringes.

25. (Currently Amended) The kit according to ~~any of the claims 20 to 24~~ claim 20, wherein said divalent or trivalent ion salts are selected from: salts of calcium, barium, strontium, zinc, aluminium, iron or chromium.

26. (Currently Amended) The kit according to ~~any of the claims 20 to 25~~ claim 20, wherein said alginate is sodium alginate.

27. (Currently Amended) A process for the preparation of capsules according to ~~any of the claims 1 to 18~~ claim 1 which comprises the following steps: a) suspension of the cells in a culture medium or in an appropriate biological liquid, optionally containing a biocompatible and/or biodegradable hydrophilic polymer; b) the addition to the suspension thus obtained of a divalent or trivalent ion salt until the attainment of ion concentrations between 1 and 500mmol/l ; c) extrusion of the cellular suspension through extruders, orifices, nozzles or needles having dimensions between 50 pm and 5000 um into an alkaline metal alginate solution in culture medium, having a concentration between 0.01%and 5% w/v, kept stirring at a speed between 10 and 200 rpm; d) optionally, cross-linking of the capsules thus formed, through interfacial polymerisation of the alginate using the cross-linking agents according to claim 5, at a temperature between5 C and40 C for a time between 1 minute and 120 minutes.

28. (Original) The process according to claim 27 further comprising the recovery stage of the capsules by filtration, the washing of the same and their suspension in culture medium.

29. (Original) The process according to claim 27 further comprising the preservation stage of the capsules under laboratory culture conditions, or by lyophilisation, refrigeration, freezing or cryopreservation.

30. (Currently Amended) The process according to ~~any of the claims 27 to 29~~ claim 27 further comprising the vehicularisation stage within said capsules of cells, tissues, tissue parts, organs, organ parts, cell

cores, gametes and embryos either freshly removed or appropriately preserved.

31. (Original) The process according to claim 30 wherein said vehicularisation stage comprises the stage of injecting or microinjecting into said capsules, cells, tissues, tissue parts, organs, organ parts, cell cores, gametes and embryos at various stages of development, either freshly removed or appropriately preserved.

32. (Currently Amended) The process according to ~~any of the claims 27 to 31~~ claim 27 further comprising the incubation stage, in an appropriate culture medium, of said capsules with cell cores, tissues, organs or parts thereof, gametes and embryos.

33. (Currently Amended) The process according to ~~any of the claims 27 to 32~~ claim 27 further comprising the stage of aspiration or removal, with any means or any technique and during any developmental stage of the cell cores, tissues or organs or parts thereof, gametes, embryos or substances produced by them.

34. (Currently Amended) The process according to ~~any of the claims 27 to 33~~ claim 27 further comprising the stage of extraction, purification, characterisation and sequencing of the substances produced such as hormones, metabolites, catabolites and other biologically active substances.

35. (Currently Amended) The process according to ~~any of the claims 27 to 34~~ claim 27 wherein, in step (a), said divalent or trivalent ion

is calcium, barium, strontium, zinc, aluminium, iron or chromium chloride or sulphate at a concentration between 5 and 200mmol/l.

36. (Currently Amended) The process according to ~~any of the claims 27 to 35~~ claim 27 wherein, in step (a), the culture medium used is selected from: physiological solution (isotonic saline), glucosate solution, Basal Medium Eagle (BME) and derivatives thereof, Hanks salts solution and derivatives thereof, tissue culture medium 199 (TCM 199) and derivatives thereof, phosphate buffered saline (PBS) and derivatives thereof, Krebs salts solution and derivatives thereof, Dulbecco modified Eagle's medium (DMEM) and derivatives thereof, tris-buffered medium (TBM) and derivatives thereof, Tyrode's salts solution and derivatives thereof, Modified sperm washing medium, modified human tubal fluid, Modified ham's F-10 medium, Upgraded B2 INRA medium, B2 INRA Menezo Medium, Upgraded B9 medium, optionally containing a biocompatible and/or biodegradable polymer which constitutes the artificial extracellular matrix.

37. (Currently Amended) The process according to ~~any of the claims 27 to 36~~ claim 27 wherein, in step (a), the medium used is TCM 199 and derivatives thereof, containing a hydrophilic polymer constituting the artificial extracellular matrix.

38. (Currently Amended) The process according to ~~any of the claims 27 to 37~~ claim 27 wherein, in step (a), the cellular sediment dilution/ polymeric solution volume ratio is between 1: 0.05 and 1: 200.

39. (Original) The process according to claim 38 wherein the cellular sediment dilution/polymeric solution volume ratio is between 1: 0.1 to 1: 100.

40. (Currently Amended) The process according to ~~any of the claims 27 to 39~~ claim 27 wherein, in step (c), the extruded cellular suspension and the alginate solution volume ratio is between 1: 1 and 1: 250.

41. (Currently Amended) The process according to ~~any of the claims 27 to 40~~ claim 27 wherein, in step (c), extrusion occurs through the use of automated, semi-automated microencapsulators, peristaltic or piston pumps or alternatives, or by the use of manually operated syringes at such a speed as to produce from 10 to 250 drops/minute.

42. (Currently Amended) The process according to ~~any of the claims 27 to 40~~ claim 27 wherein, in step (c), the extrusion, with automated, semi-automated microencapsulators, peristaltic or piston pumps or alternatives, or by the use of manually operated syringes, occurs at such a speed as to produce 60 drops/minute.

43. (Currently Amended) The process according to ~~any of the claims 27 to 40~~ claim 27 wherein, in step (c), the extrusion of the cellular suspension occurs through the use of needles with internal diameters between 300pm and 2000 um.

44. (Currently Amended) The process according to ~~any of the claims 27 to 43~~ claim 27 wherein, in step (c), the alginate solution is kept

stirring at a speed between 20 and 100 rpm and has a concentration between 0. 1% and 1% w/v.

45. (Currently Amended) The process according to ~~any of the claims 27 to 44~~ claim 27 wherein, in step (c), the extruded cellular suspension and the alginate solution volume ratio is between 1: 15 and 1: 50.

46. (Currently Amended) The process according to ~~any of the claims 27 to 45~~ claim 27 wherein said alginates, in a2% solution in water and at a temperature of25 C, have a viscosity between 200 cP and 20000 cP.

47. (Currently Amended) The process according to ~~any of the claims 27 to 46~~ claim 27 wherein steps (a), (b) and (c) are performed at a temperature between5 C and40 C.

48. (Currently Amended) The process according to ~~any of the claims 27 to 47~~ claim 27 wherein steps (a), (b) and (c) are performed at a temperature between20 C and30 C.

49. (Currently Amended) The process according to ~~any of the claims 27 to 46~~ claim 27 wherein step (d) is performed at a temperature between5 C and40 C, for times between 1 minute and 120 minutes.

50. (Currently Amended) The process according to ~~any of the claims 27 to 46~~ claim 27 wherein step (d) is performed at a temperature between20 C and30 C, for times between 3 minutes and 30 minutes.